Airway obstruction in children with congenital hypoplasia of the mandible.

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Children with congenital mandibular hypoplasia are at risk for development of airway obstruction.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26550

Bron
NTR

Verkorte titel
CMH

Aandoening

Congenital mandibular hypoplasia

Ondersteuning

Primaire sponsor: Erasmus University Medical Center
Overige ondersteuning: Erasmus University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Outcomes of physical examination:
1. Length in centimetres;
2. Head circumference in millimetres;

3. Weight in kilograms.

Outcomes of polysomnography:
1. Apnea Hypopnea Index (AHI);
2. Oxygen Desaturation Index (ODI).

Outcomes of ENT exam and nasoendoscopy:
1. Malampatti score;
2. Cormack-Lehane score;
3. Sher-classification.

Outcomes of measurements on:
1. Distances in millimetres.

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of this study is to establish the relation between congenital mandibular hypoplasia and upper airway obstruction using a prospective cohort and cross-sectional study design. Furthermore, we aim to analyse the craniofacial growth pattern, feeding problems and mandibular distraction outcome in children with congenital mandibular hypoplasia. Also we will determine the reliablity of ultrasonography compared to 3D-CT scans in measurement of the mandible.

Doel van het onderzoek

Children with congenital mandibular hypoplasia are at risk for development of airway obstruction.

Onderzoeksopzet

Exams in both study population 1a / control population 1 b / control population 2 will take place at the age of 3 months, 6 months, 9 months, 1 year, 2 years, 3 years, 4 years and 6 years old.

Exams in study population 1b / control population 1b are cross-sectional and will consist of one study visit.

Exams in study population 2 are cross-sectional and will take place directly after the 3D-CT

scan.

Onderzoeksproduct en/of interventie

This will be an invasive observational study in which patients in both study population 1a and control population 1a / 2 will undergo a number of exams and tests to address objectives 1a / 1b / 2a / 2b. The test and exams are:

1. Polysomnography (for the detecting of OSA, two clinical PSG's in the first year, and thereafter an ambulant PSG once a year);

2. Endoscopy (to assess the type and severity of airway obstruction, in the first year);

3. Lateral skull X-ray (to assess the skull morphometrics, when the child is > 6 year on an annual basis);

4. Ultrasonography (to assess mandibular growth, annually);

5. Jaw-index (to assess mandibular growth, annually);

6. OSA-18/OSA-12 (to assess presence of OSA and QOL, annually).

For the reliabity and validity study of ultrasonography all children in study population 2 (who undergo a 3D-CT scan as part of regular patient care) will get an ultrasound exam of the mandible.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Study Population 1a:

1. Age between 0 and 3 months;

2. Presence of a congenital mandibular hypoplasia.

Study Population 1b:

1. Age between 3 months and 18 years old;

2. Presence of congenita mandibular hypoplasia.

Study population 2:

1. Below the age of 18 years old;

2. 3D CT-scan of the head as part of regular patient care.

Control Population 1a:

1. Age below 3 months;

2. Presence of cleft palate;

3. No congenital mandibular hypoplasia.

Control population 1b:

1. Age between 3 months and 18 years old;

2. Presence of cleft palate.

Control Population 2:

1. Age below 3 months;

2. Presence of an immature breathing pattern, but otherwise healthy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-10-2012
Aantal proefpersonen:	525
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-02-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37826
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3163
NTR-old	NTR3307
CCMO	NL37895.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37826

Resultaten

Samenvatting resultaten
N/A